104TH CONGRESS
1ST SESSION

S. 955

To clarify the scope of coverage and amount of payment under the medicare program of items and services associated with the use in the furnishing of inpatient hospital services of certain medical devices approved for investigational use.

IN THE SENATE OF THE UNITED STATES

JUNE 22 (legislative day, JUNE 19), 1995

Mr. HATCH (for himself, Mr. GREGG, Mr. FRIST, Mr. KENNEDY, Mrs. KASSEBAUM, Mr. GRAMS, Mr. WELLSTONE, Mr. CHAFEE, Mrs. HUTCHISON, and Mr. D'AMATO) introduced the following bill; which was read twice and referred to the Committee on Finance

---

A BILL

To clarify the scope of coverage and amount of payment under the medicare program of items and services associated with the use in the furnishing of inpatient hospital services of certain medical devices approved for investigational use.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Advanced Medical Devices Access Assurance Act of 1995''.

SEC. 2. CLARIFICATION OF MEDICARE COVERAGE OF ITEMS AND SERVICES ASSOCIATED WITH CERTAIN MEDICAL DEVICES APPROVED FOR INVESTIGATIONAL USE.

(a) COVERAGE.—Nothing in title XVIII of the Social Security Act may be construed to prohibit coverage under part A or part B of the medicare program of items and services associated with the use of a medical device in the furnishing of inpatient hospital services (as defined for purposes of part A of the medicare program) solely on the grounds that the device is not an approved device, if—

(1) the device is an investigational device; and

(2) the device is used instead of either an approved device or a covered procedure.

(b) CLARIFICATION OF PAYMENT AMOUNT.—Notwithstanding any other provision of title XVIII of the Social Security Act, the amount of payment made under the medicare program for any item or service associated with the use of an investigational device in the furnishing of inpatient hospital services (as defined for purposes of part A of the medicare program) may not exceed the amount of the payment which would have been made under the program for the item or service if the item or service were associated with the use of an approved device or a covered procedure.

SEC. 3. DEFINITIONS.

In this Act—

(1) the term ''approved device'' means a medical device which has been approved for marketing under pre-market approval under the Federal Food, Drug, and Cosmetic Act or cleared for marketing under a 510(k) notice under such Act; and

(2) the term ''investigational device'' means a medical device (other than a device described in paragraph (1)) which is approved for investigational use under section 520(g) of the Federal Food, Drug, and Cosmetic Act.

○